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Addressing tobacco smoking and drinking to improve TB treatment outcomes, in South Africa: a feasibility study of the “*ProLife*” programme

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Conflicts of interest

GM Louwagie, N Morojele, K Siddiqi, ND Mdege, MC Engelbrecht, J Tumbo, O Omole, MO Bachmann, OA Ayo-Yusuf received a research grant (MRC-RFA-02: TB -05-2015) to execute the research project. The National Research Foundation of South Africa funded conference attendance for GL (Incentive Funding for Rate Researchers, Grant No. 109318). GL has received a monthly remuneration of ZAR 10 000,00 (700 US dollars) per month from 1 October 2018 until the present moment for academic work on the Prolife project.

Human rights

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments. Ethics clearance was obtained from the Ethics committees of Sefako Makgatho Health Sciences University (SMUREC/D/77/2016:IR), the University of York's Department of Health Sciences (20/05/2016), the University of Pretoria (119/2016), the University of the Witwatersrand (MI60455), the University of the Free State (HSREC-71/2016) and the South African Medical Research Council (EC010-4/2016). Trial registration: ISRCTN ID ISRCTN62728852 (<http://www.isrctn.com/ISRCTN62728852>)

Informed consent

Informed Consent was obtained from all individual participants included in the study.

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training; Ms M Machaea-Malinga for coding the counselling transcripts; Mr M Sebola for overall administrative support; and Mr A van Zyl for research support.

Implications

Practice: A combination of motivational counselling and short messages targeting alcohol intake, tobacco smoking and treatment adherence delivered by lay counsellors, is a feasible intervention that may improve tuberculosis treatment outcomes. Ongoing monitoring of intervention fidelity and training of counsellors is essential.

Policy: If the proposed intervention proves to be effective in a larger trial, policymakers should aim to build tobacco cessation and alcohol reduction strategies into TB control programmes.

Research: Future research should be aimed at determining the effectiveness and cost-effectiveness of the proposed intervention in a large randomised controlled trial.

Addressing tobacco smoking and drinking to improve TB treatment outcomes, in South Africa: a feasibility study of the ProLife programme

Abstract

Background: Alcohol and tobacco use may lead to negative treatment outcomes in tuberculosis (TB) patients, and even more so if they are HIV-infected. We developed and tested the feasibility of a complex behavioural intervention (ProLife) delivered by lay health workers (LHWs) to improve treatment outcomes in TB patients who smoke tobacco and/or drink alcohol, at nine clinics in South Africa. **Methods:** The intervention comprised three brief motivational interviewing (MI) sessions augmented with a Short-Message Service (SMS) programme, targeting as appropriate: tobacco smoking, harmful or hazardous drinking and medication adherence. Patients received SMS-messages twice a week. We measured recruitment and retention rates and assessed fidelity to the MI technique (MI Treatment Integrity 4.1 tool). Lastly, we explored LHWs' and patients' experiences through interviews and semi-structured questionnaires, respectively. **Results:** We screened 137 TB patients and identified 14 smokers, 13 alcohol drinkers and 18 patients with both behaviours. Participants' mean age was 39.8 years, and 82.2% were men. The fidelity assessments pointed to the LHWs' successful application of key MI skills, but failure to reach MI competency thresholds. Nevertheless, most patients rated the MI sessions as helpful, ascribed positive attributes to their counsellors, and reported behavioural changes. SMS-messages were perceived as reinforcing but difficult language and technical delivery problems were identified as problems. The LHWs' interview responses suggested that they (a) grasped the basic MI spirit but failed to understand specific MI techniques due to insufficient training practice; (b) perceived ProLife as having benefitted the patients (as well as themselves); (c) viewed the SMS messages favourably; but (d) considered limited space and privacy at the clinics as key challenges. **Conclusions:** The ProLife programme targeting multiple risk behaviours in TB patients is acceptable but LHW training protocol, and changes in wording and delivery of SMS messaging are necessary to improve the intervention.

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Key Words: Tuberculosis, mHealth, Motivational Interviewing, Tobacco cessation, Alcohol use, Medication adherence

Background

South Africa has the highest tuberculosis (TB) incidence rate out of 30 high TB-burden countries in the world [1]. Successful TB treatment is compromised by high rates of treatment interruption, drug resistance and deaths [1]. TB patients who are HIV-positive are at greater risk of dying, but early antiretroviral treatment (ART) initiation greatly reduces this risk [2]. Successful TB treatment can also be compromised by lifestyle behaviours. In particular tobacco use and problem drinking are common among TB patients [3-5]. Both smoking and alcohol use increase the risk of death and poor treatment adherence for TB patients [6, 7]. Tuberculosis patients who smoke tobacco have treatment failure more often and are prone to relapse [8]. Furthermore, patients who are co-infected with TB and HIV, and who smoke, are predisposed to many HIV-related complications [9]. In addition tobacco smoking and alcohol consumption are associated with reduced ART initiation and adherence [10, 11], which also negatively influences clinical response to treatment. There is thus a need to address smoking and drinking in patients with TB and HIV co-infection.

Brief smoking cessation interventions are effective and affordable in low-income countries, both for TB patients and other smokers [12-14]. Disease diagnosis can constitute a 'teachable moment', therefore TB patients are more likely to be receptive to interventions and more likely to succeed in quitting smoking and moderating alcohol use, compared to general smokers and problem drinkers [15]. Due to the widespread comorbidity of TB with communicable and non-communicable diseases, scientists have advocated that TB control efforts integrate with general health care services [16, 17], which include treatment for addiction. Addressing smoking and alcohol misuse in TB patients can have clear short- and medium-term benefits [9, 18]. TB patients who stop smoking show a reversal of immunological abnormalities within six weeks of cessation and could have a greatly reduced risk of death due to TB. Although many studies have separately evaluated the effectiveness of tobacco

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cessation, alcohol reduction or adherence interventions in TB patients [19, 20], only a few have considered joint interventions for multiple behaviours to improve treatment outcomes [21, 22] even though these behaviours often co-exist in the same patients [4, 5].

To our knowledge, no studies have reported on interventions that use Motivational Interviewing (MI), a patient-centred counselling approach, to address multiple behavioural problems that negatively impact TB outcomes. Motivational interviewing is a counselling style that helps patients to explore and resolve ambivalence aimed at changing behaviour [23]. This counselling technique has been used effectively to reduce hazardous drinking, effect tobacco cessation, and improve TB treatment or ART adherence [13, 24-26]. Motivational interviewing can be adapted for use in busy clinical practices [27] and even single session interventions have been successfully used by lay health workers (LHWs) to effect behaviour change [13]. Mobile phone technology using SMS messages can also enhance ART adherence and smoking cessation interventions [28, 29] and potentially promote adherence to TB treatment [30].

Given the potential benefits of MI and SMS-messages to reduce smoking and alcohol use by TB patients, we designed the ProLife programme. This programme aims to improve TB treatment outcomes by modifying life-style behaviours through a brief motivational intervention and SMS-programme. We tested the feasibility of this programme in a group of TB patients that used tobacco, drank alcohol or did both, by (a) monitoring fidelity to MI sessions and assessing the proficiency of LHWs in facilitating the MI sessions; (b) evaluating the experiences of TB patients and LHWs with the interventions; and (c) determining enrolment and follow-up rates of TB patients in the study.

Methods

Design

We used the United Kingdom Medical Research Council guidelines for developing and evaluating a complex intervention as a guide [31]. First we developed a conceptual framework based on existing evidence of behavioural factors that

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

influence TB treatment outcomes (Figure 1). We then used mixed methods - described in the methods section- to determine the intervention fidelity, acceptability and likely enrolment and retention rates of the future trial.

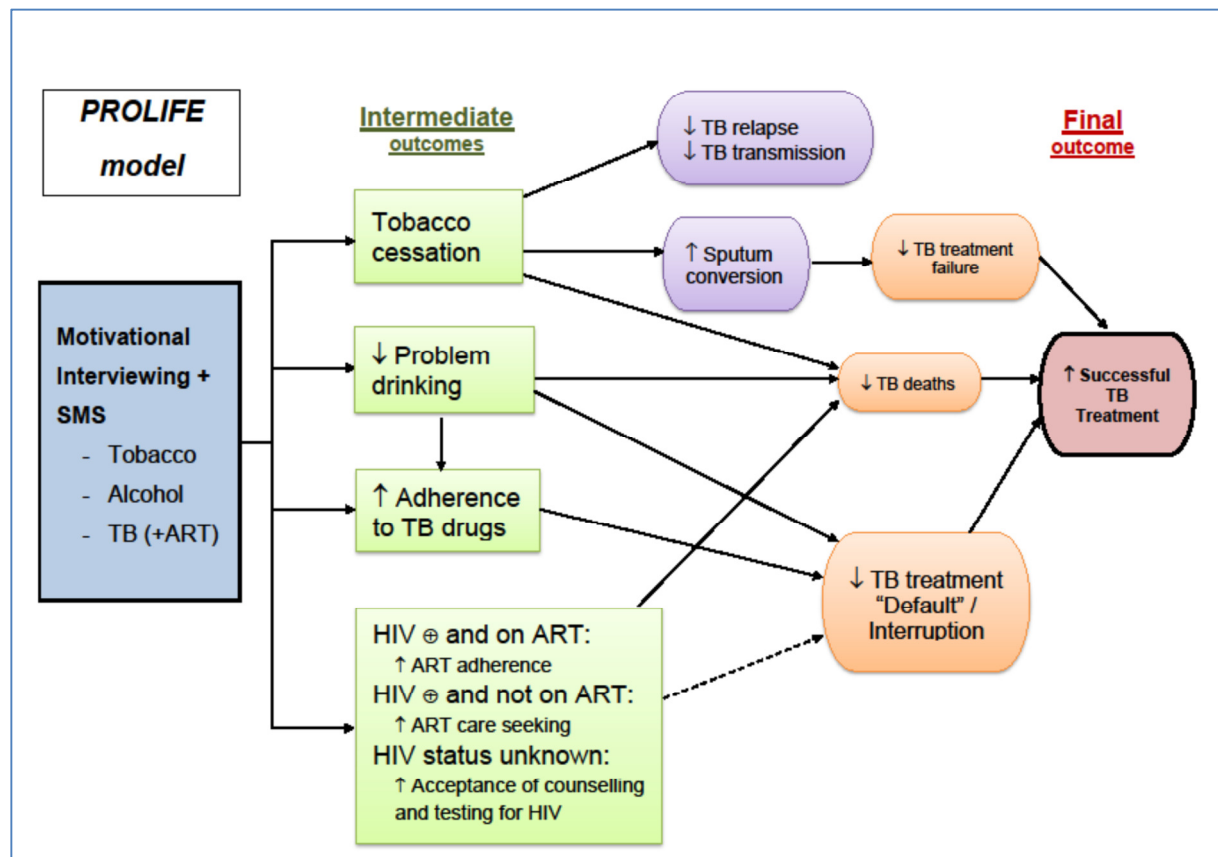


Figure 1: Conceptual framework of the ProLife programme to reduce smoking and alcohol consumption in TB patients and potential impact on TB treatment outcomes.

Study setting

This study was conducted in one health district in each of three South African provinces (Free State, Gauteng and North West), in three clinics per district.

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

Study participants

Participants were adults who were due to start TB treatment, or who had been on treatment for less than one month for the current TB episode for bacteriologically or clinically confirmed drug sensitive pulmonary TB (PTB) [32]. Eligible patients included current smokers, defined as having smoked any tobacco in the past month, and hazardous or harmful drinkers. We identified hazardous drinkers according to the Alcohol Use Disorders Identification Test [AUDIT] score ≥ 8 for men or ≥ 7 for women and < 16 for hazardous drinking and between 16 and 19 for harmful drinking [33]. Patients who smoked and drank alcohol were also enrolled. We did not enrol dependent drinkers, defined as those with an AUDIT score > 19 , but referred them for specialist treatment and intensive intervention. However, we retained patients who were both alcohol dependent (AUDIT > 19) and smoked because their smoking could be amenable to the MI intervention. These participants received the smoking cessation intervention for their tobacco smoking but specialist referral for their alcohol problems. We excluded patients who did not possess a functioning cell phone, were too ill to be interviewed or did not speak any of the languages used in the exit questionnaires (English, Isizulu, Sesotho and Setswana).

To measure fidelity to the MI counselling intervention, we randomly sampled one patient enrolled between 15 November 2016 and 30 February 2017 for each LHW. Random selection was chosen to reduce bias introduced by knowledge of being observed. If a selected patient did not have three recordings of counselling sessions, we selected the next available patient.

Lay health workers delivered the intervention and also participated in exit interviews. The criteria used to select LHWs are described in the next section.

The ProLife intervention programme package

Motivational Interviewing (MI)

Motivational Interviewing is an approach in which the counsellor helps the client to explore motivation and confidence to change harmful behaviours and, to identify suitable ways to deal with obstacles to behaviour change [23]. The five guiding principles of MI are (a) expressing empathy, (b) developing discrepancy, (c) avoiding

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

argumentation, (d) rolling with resistance, and (e) supporting self-efficacy [34]. We opted for a brief MI approach [27] as the programme had to be feasible in the resource constrained environments of busy TB clinics in South Africa, and other low and middle-income countries. The recommended duration of an MI session was 20 minutes.

Eligible LHWs had completed high school and completed the nationally prescribed 56 days training for community health workers, which included a large section on HIV and TB treatment and care. Eligible CHWs also had at least one year of previous relevant HIV- or TB-related counselling experience. Until recently different categories of LHWs were employed in the South African public health services. They fulfilled – amongst others- roles as lay HIV counsellors and TB treatment support workers. The South African Department of Health is currently integrating the different LHW cadres into one single cadre. For this study we recruited nine LHWs who had not or not yet been absorbed into the new LHW body [35].

During an expert review workshop, we compiled background information on tobacco cessation, problem drinking and factors that influence adherence, and agreed on the framework of the MI counselling intervention. An experienced, certified MI facilitator then developed a detailed training manual in collaboration with the experts and trained the LHWs in a five day workshop. In the first intervention session - at the start of TB treatment - LHWs established rapport and determined the participant's tobacco smoking, problem drinking and other potential obstacles and facilitators for treatment adherence. With the support of the LHW the patient then identified his/her priority problem for change (namely alcohol, tobacco or medication adherence), thus setting the agenda for change. This agenda for change could include a plan to quit tobacco smoking, reduce drinking or deal with other perceived obstacles relating to treatment adherence or initiation. The LHW also informed the patient about the nature and frequency of the upcoming SMS messages. The second MI session built on the previous session, dealt with challenges relating to the previously set agenda, and then proceeded to the next behavioural problem. The third session either dealt with the final identified problem or reinforced the previous message. The one-to-one

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

counselling sessions were reinforced by SMS-messages, supporting tobacco cessation, alcohol use and medication adherence.

SMS-programme

The tobacco cessation and TB-related messages were selected and adapted from an SMS-bank developed by the World Health Organisation as part of their “Be He@lthy Be Mobile programme” [36]. The research team developed the alcohol-related messages during an expert workshop. We based the content of the SMS-messages on the Information-Motivation-Behavioural Skills programme as adapted for TB [37, 38]. For example, to target smoking cessation, we sent the message “Within 1 month of quitting, you will cough less and breathe easily” to provide information and motivate the participant to quit. TB-related messages also included some messages that were not directly related to TB medication-adherence but to infection risks, as they may motivate participants to take their treatment to protect family members. The complete set of messages is presented in Table 1. Professional translators translated the SMS-messages into the three most common local languages and we formatted the messages to comply with SMS character limitations. Study patients received 10 TB-related messages followed by seven alcohol reduction- and/or seven smoking cessation-related messages, as appropriate. The SMS-stream was automatically system-generated one day after the first MI session and was delivered twice a week for up to 12 weeks (Figure 2). It was technically not feasible for our SMS service provider to tailor the SMS text message order to match the order of the individual patient’s MI sessions.

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TBM 2019;XX:XX-XX doi:10.1093/tbm/ibz100

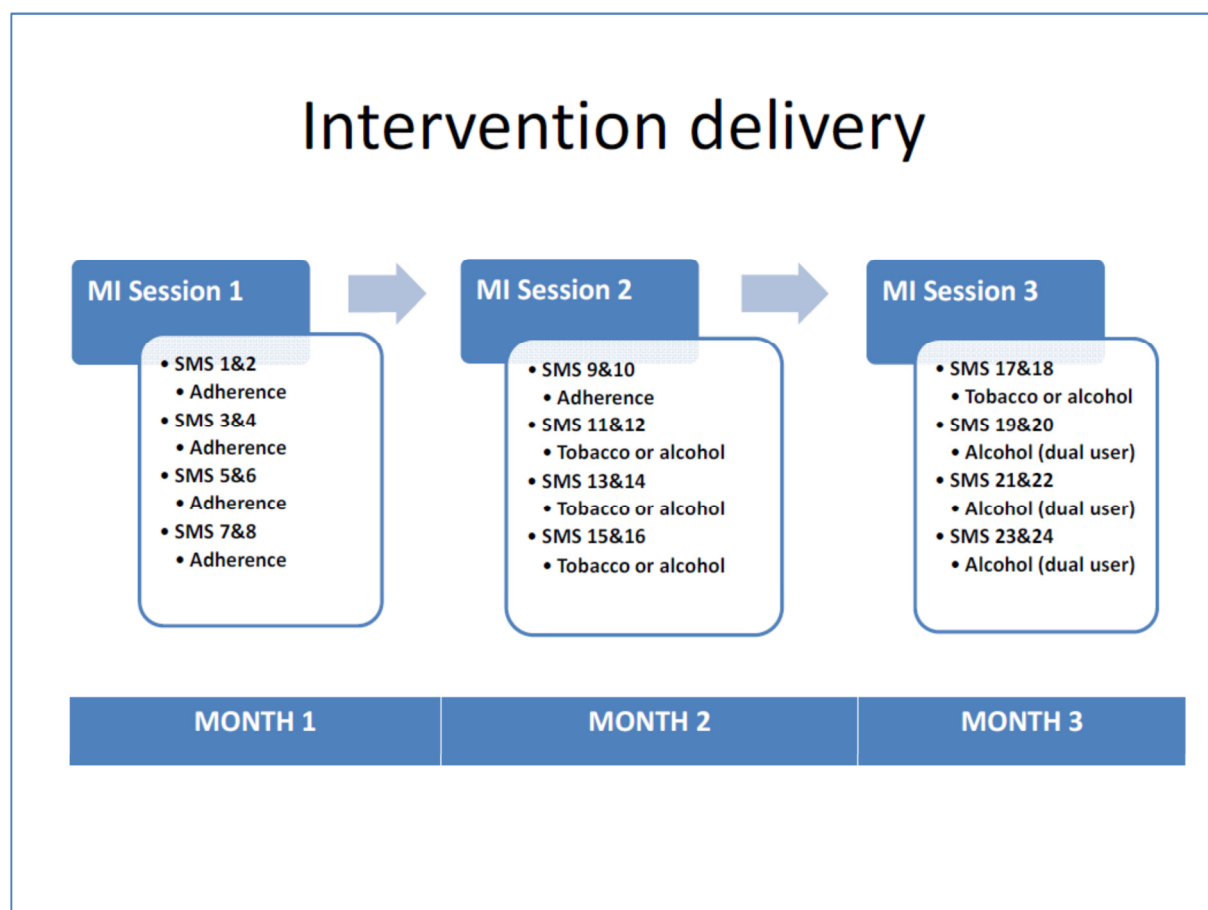


Figure 2. Delivery of the ProLife intervention to stop smoking and reduce the consumption of alcohol in newly diagnosed TB patients.

Measurements and data collection

Between 15 November 2016 and 30 March 2017, fieldworkers identified eligible TB patients at respective TB clinics, using a screening questionnaire, and scheduled three MI sessions: at enrolment, at one month and at two months. Attempts were made to schedule the MI counselling appointments on the same day as patients' TB treatment appointments. Patients received SMS-reminders of planned and missed visits. District study coordinators and fieldworkers (not involved with MI counselling) contacted patients who missed planned visits. The MI sessions were audio-recorded - with participant permission - for later assessment of treatment fidelity.

After patients' third MI session, district study coordinators interviewed them using a semi-structured questionnaire in their preferred language, to determine their

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

experiences with the counselling, the counsellors and the SMS-programme. The patient questionnaire was developed specifically for this study and consisted of structured questions with binary or Likert-type response options and a few open questions.

Each LHW was interviewed by a trained Master's degree student (LP), using an open-ended question format after they had completed counselling sessions with at least three TB patients, where possible. The interview topics included: LHWs' experiences with MI delivery, their perceptions regarding the SMS-programme, the perceived impacts of MI on the patients, and their overall experiences with the ProLife project. The interviews were audio-recorded and translated into English.

Data management and analysis

Quantitative data from the semi-structured questionnaires with TB patients were analysed with Stata Statistical package version 14 [39]. Data were descriptively analysed with percentages, means and standard deviation or medians and interquartile ranges, as appropriate.

Qualitative data from the exit interviews with LHWs were transcribed. They were then thematically analysed using a deductive "top down" approach [40] owing to the need to answer specific questions related to the feasibility and acceptability of the intervention based on the LHWs' (as intervention deliverers) impressions. We took the following steps in analysing the data: familiarization with the data by reading and re-reading the transcripts, generation of codes, development of themes, and reviewing and refining themes [40]. Two researchers independently identified the themes and compared results until the final sets of themes were incorporated. From the vast amount of qualitative data obtained and analysed, we present the findings that are most pertinent to the questions of the intervention's feasibility and acceptability [41] and that can highlight changes that would be needed to the intervention in the main trial.

Counselling sessions were audio-recorded, transcribed, translated and coded independently by two researchers. To assess MI fidelity, coders listened directly to the audio-recordings in the original language and read through the transcribed and

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

translated transcripts. The fidelity of the MI intervention was determined with the MI Treatment Integrity tool version 4.1 [42, 43]. This tool consists of two components viz. “global ratings” and “behaviour counts”. The “global ratings” allow the coder to assess, on a 5-point Likert scale (1 for low and 5 for high), how well or poorly the counsellor adheres to the MI practice. Ratings are conducted on four items, divided into Technical Components (Cultivating change talk and Softening sustain talk) and Relational Components (Partnership and Empathy). Scores on Cultivating Change Talk and Softening Sustain Talk are averaged to obtain the Technical global scores while scores on Partnership and Empathy are averaged to obtain Relational global scores. The basic competency threshold scores for Technical and Relational scores are 3 and 3.5, respectively. The “behaviour counts” involve counting 10 verbal behaviours of the counsellor during the intervention: Giving Information, Persuade, Persuade with permission, Asking questions, Simple reflections, Complex reflections, Affirm, Seeking collaboration, Emphasizing autonomy and Confront. Counts involve simply adding the number of statements that fall in a certain category. “MI adherence” is determined by adding up the following verbal behaviours: Seeking Collaboration, Affirm and Emphasizing autonomy. “MI non-adherence” is determined by summing instances of Confront and Persuade. No thresholds for MI adherence or non-adherence are specified in the MITI 4.1 manual [43]. The Reflection-to-Question (R:Q) ratio and Percentage of Complex Reflections (% CRs) are also determined. One reflection to each question is considered a “fair” practice level while two reflections to each question is considered a “good” practice level. A fair and a good % CRs are 40% and 50%, respectively. Individual and summary scores were calculated for each coder as well as for both coders together. The intra-class correlation, using the two-way mixed model with absolute agreement, was used as a measure of interrater reliability for the summary measures.

Ethical considerations

Ethics clearance was obtained from the Ethics committees of Sefako Makgatho Health Sciences University (SMUREC/D/77/2016:IR) and from the other five participating research institutions. Informed consent was obtained from all individual participants (both TB patients and LHWs). TB patients received ZAR 60 (about 4 USD) reimbursement for each study visit. The Prolife study was registered in the Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

ISRCTN registry with study ID ISRCTN62728852. Participants with serious social or mental health problems were referred to a social worker, clinical psychologist or psychiatric care; whichever was available.

Results

Enrolment and follow-up of study patients

Enrolment and follow-up figures are presented in Figure 3. Out of 141 TB patients approached to participate in the study, 137 consented to screening, of which 92 were excluded for reasons listed in Figure 3. The most common reason for exclusion was having already been on TB treatment for more than one month. Only 21 patients were excluded because they did not smoke cigarettes or drink alcohol to excess. Eventually 45 patients were enrolled.

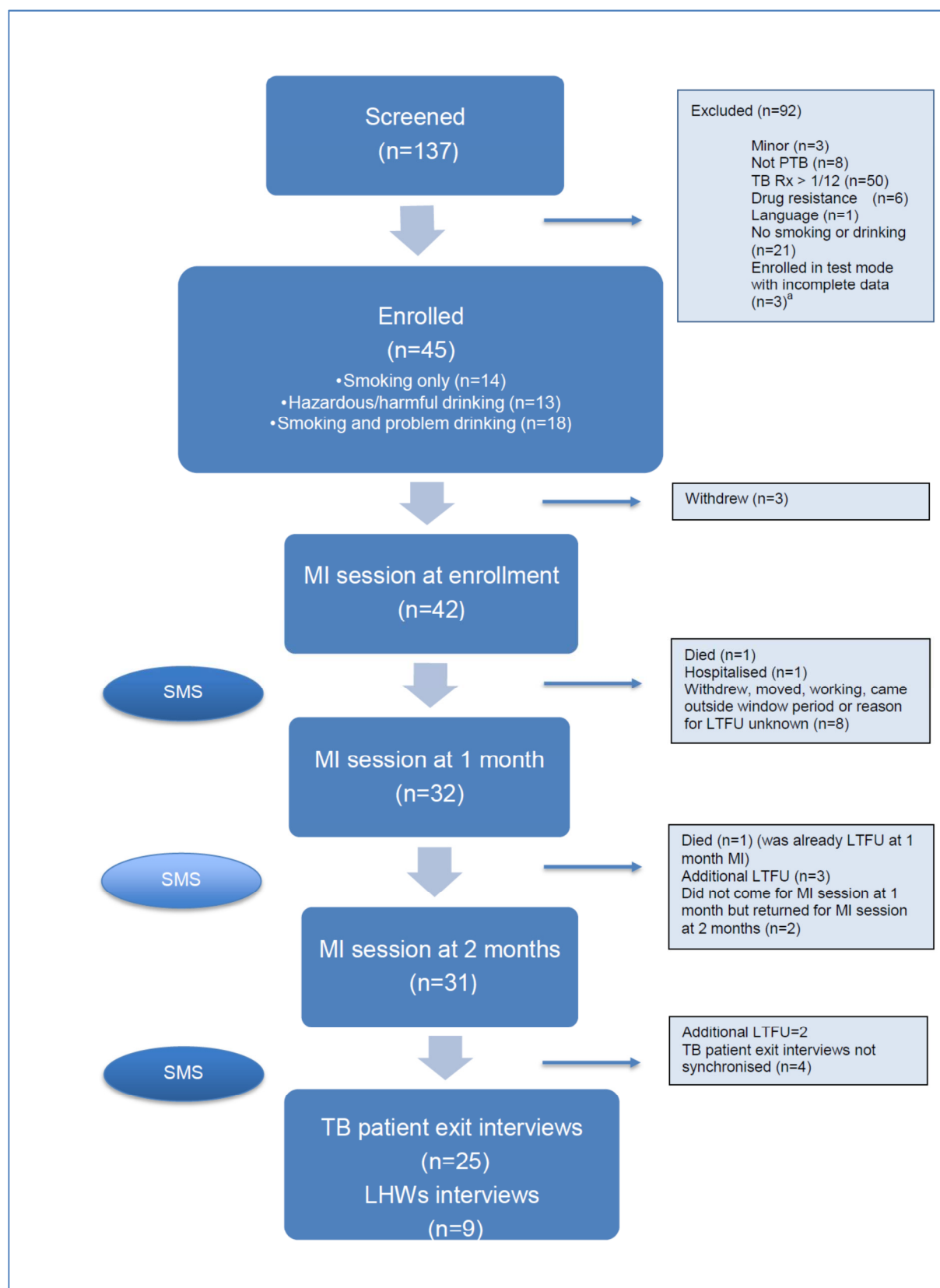


Figure 3. Screening, enrolment and follow-up of patients with TB who smoked cigarettes or drank alcohol.

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

^aThree patients were enrolled in cell phone test mode and their data could not be fully recovered. They also received incomplete SMS-messages. They were excluded from the study; TB Rx > 1/12: TB treatment for greater than one month; LTFU: Loss to follow-up.

Patients were on average 39.8 years old (SD 13.3) and most were male (82.2%). Nearly one third of the patients were eligible because of exclusively drinking (28.9%), 31.1% because of exclusively smoking and 40.0% for concurrently drinking and smoking. Nearly all patients (93.3%) received their first MI counselling session, but close to 30% failed to receive their second or third MI session due to various reasons (Fig 3). Two patients died due to causes that were unrelated to the study: one between baseline and one month follow-up and one between one and two months follow-up (Fig 3).

Motivational interviewing fidelity

We analysed the fidelity of 22 MI sessions (out of a target number of 27 sessions). Two recordings (one for two different LHWs each) were not audible, for two sessions the patient declined permission to record, and one recording could not be retrieved. The random selection of one patient per LHW for the fidelity assessments led to selection of the first patient to be counselled in the case of two LHWs; the second patient for three LHWs; and the third patient for four LHWs. The recorded sessions lasted from 5–26 minutes (Mean = 18 minutes; SD = 5.8). The MITI tool recommends that a section of 20 minutes is analysed to determine the fidelity. Where the session was shorter than 20 minutes, the entire session was analysed.

In terms of the global ratings (see Table 2), the LHWs' counselling sessions were generally below proficiency levels on Cultivating Change Talk and Partnership (defined as mean score below 2). Scores were however better for Softening Sustain Talk. The LHWs' counselling sessions did not achieve the basic proficiency threshold of 3.5 for the Relational component (Partnership + Empathy). Their mean score on the Technical component (Cultivating Change Talk + Softening Sustain Talk) was also below the threshold of 3 for both coders. However, the interquartile ranges

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

(IQRs) of the global rates suggest wide variation in the quality of the MI sessions with the upper quarter of the IQR reaching close to proficiency levels (Table 2).

For behavioural counts, “Asking Questions” had the highest mean score (more than 16) for both coders, followed by “Simple Reflection” with an average mean score of 4.9. The counsellors did not perform well on the following domains: Giving Information, Complex Reflections and Seeking Collaboration (Table 2). The overall % Complex Reflections threshold of 40% was not reached. The mean Reflections to questions ratio was 0.4, which did not meet the fair or good competency and proficiency ratios of 1:1 and 2:1, respectively. The LHWs made on average 5.5 MI adherent (Affirm, Emphasize Autonomy and Seek Collaboration) and 3.3 non-adherent (Confront and Persuade) statements.

Other problems that were identified from listening to the recordings were that LHWs struggled to set the agenda at the beginning of the sessions and evoke change talk. Some of the LHWs dealt with three target goals (smoking, alcohol and medication adherence) all at once and were unable to focus and direct the session effectively. Furthermore, many LHWs struggled with use of the “ruler” on which patients were asked to indicate their motivation and confidence to change, on a 10-point scale.

The interrater reliability of the two coders over all three sessions was in the excellent range for the total number of MI adherent (Intraclass Correlation Coefficient [ICC]: 0.96) and MI non-adherent behaviors (ICC: 0.97). The interrater reliability was moderate for Relational scores (ICC 0.67) and good for Technical scores (ICC 0.82) (Table 2).

TB patients’ experiences with the Prolife intervention: questionnaire results

We administered the questionnaire to 29 patients, but data were missing for four patients for whom electronically captured data did not synchronise at the level of the data server and could therefore not be retrieved. As shown in Table 3, most patients rated the intervention sessions as “helpful”, “somewhat helpful” or “very helpful”. All patients reported enjoying the sessions “quite a lot,” “very much” or “a great deal”. About half of the patients reported reduced smoking and drinking. Most patients

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

reported feeling better emotionally and physically and better adherence to TB treatment. All patients reported liking the counsellors' style of interacting "quite a lot", "very much", "a great deal", and patients ascribed many positive attributes to the counsellors while rarely endorsing any listed negative attributes (Table 3). Responses to the open-ended questions supported the trends from the closed questions. None of the patients reported challenges with the counsellors. They were satisfied overall with the programme and expressed happiness in participating, but also mentioned a few shortcomings of the intervention. For example, several patients did not like the counselling sessions being recorded. The TB patients' experience with the SMS-messages was also positive overall, as indicated by their responses to the exit interview questions shown in Table 4. However, some of them struggled to understand some messages, or had technical problems with their phone or with the SMS-delivery. For example, some patients received many messages at once or none at all. However, most patients indicated that they would have liked to receive messages for a longer time period (Table 4).

LHWs' experience of the Prolife intervention: themes from interviews

MI Delivery: The most pertinent themes that were identified from the LHWs' accounts regarding MI delivery were that they had grasped the overall spirit of MI, that they did not know how and when to implement some specific MI techniques, and that the MI training and opportunities for practicing had been limited. For example, one LHW described her experience of the MI approach as follows:

"The things I was able to do even after training were open-ended questions, affirmation, reflecting and making a summary of what the client is telling me, but the problem is I could not put them in order."

Another common challenge was not knowing how to deal with patients who denied using tobacco or alcohol. The LHWs felt positive overall about the training received but felt unprepared for the diversity of problems, attitudes and beliefs that patients presented with. They felt that they needed additional practice to enable them to more confidently implement the MI intervention. The following quote is illustrative:

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

“...everything was done well in the training, because at the training it’s simple to answer questions and now when it comes to the counseling it’s a challenge because you get different clients depending on their problems, so if you practice more it could help, (...)”

Perceived Impact of the Prolife Programme: The LHWs reported numerous ways in which they believed patients benefited from being in the programme. These included observing improvements in patients’ general physical and mental health, their TB, and also in their knowledge, motivation to change and actual change in drinking and tobacco smoking behavior. The following quotes exemplify this observation:

“The first patient, like he was literally crying, and he explained to me that he has difficulty because he lives alone and feels lonely and is suicidal, so he felt if the programme gets terminated there won’t be anyone who will listen to him. So I think MI has a big impact on people’s lives, (...). Like he was happy as if I did something and all I did was sit and acknowledge him. (...) so people really need MI because there is no one who talks to them at home, (...).”

SMS Messages: The LHWs’ narratives suggested that they had an overall positive view about the SMS-messages. They felt that the SMS-messages complemented the ProLife programme in a number of ways, such as by reminding them about the facts and information imparted and behavior change(s) agreed upon.

“According to me I think they (MI and SMS) are both important because patients are happy that we talk to them verbally and again send SMSs that remind them of the important comments”

They however felt that the SMS-messages might not be suitable for patients who do not own phones or had to rely on others to access their messages.

Overall Assessment of the ProLife Intervention: The LHWs’ assessments of the intervention were overall positive, although they also noted some challenges. They were pleased by patients’ apparent appreciation of being in the intervention; an impression that stemmed from the LHWs’ observation of patients’ visits to the sites

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and their attendance at the initial and follow-up counseling sessions; as indicated by this LHW's comments:

"The things I liked are that the patients were happy. Most of them were on time for the session, and they would come when we were busy recruiting (...) just to pass their greetings. They would be happy just to see that there are people who care and want to see them cured and feeling good."

The LHWs felt that there is widespread need for a ProLife intervention and they were very positive about their experiences in the project as a whole. One LHW described her feelings as follows:

"I like knowing about the new counselling programme. It helped me not only to help people who are sick but in life in general, (...). Also the fact that I was making a difference in people's lives, like sometimes nurses shout at them (patients) and when they think of going back to the clinic to come across the rude nurse again they rather stay home, (...)."

However, the LHWs assessed the limited space and privacy for sessions in the clinics as challenging. They were also concerned about the well-being of very ill patients and becoming infected with TB in TB clinic settings. They also felt that the use of tape recorders hindered free participation by some of the patients.

Discussion

This study's findings are in support of the relevance of addressing smoking and drinking in TB patients, in particular in male TB patients. Eighty percent of our study participants were male. This male predominance differs from general TB statistics in South Africa in which on average only about half of all the TB patients are men [4]. Smoking and drinking is therefore particularly prevalent in male TB patients and warrants specific attention for counselling on alcohol and tobacco in this patient group [13]. Both tobacco smoking and problem drinking were relatively common in newly diagnosed TB patients with more than a third of the enrolled patients concurrently smoking and drinking alcohol. The clustering of addictive behaviours in

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our study is consistent with findings in the published literature [44]. Recent evidence suggests that multiple risk behaviour interventions similar to the ProLife programme, can be effective and that sequentially addressing smoking alongside other interventions as used in ProLife is preferable to simultaneous interventions [45].

Even though MI was positively received, LHWs were not fully confident with using all of the specific techniques and tools and did not achieve the desired MI proficiency. One of the possible explanations is that thresholds recommended in the MITI 4.2 guidelines are designed for full-length MI sessions and may not necessarily be appropriate for brief MI sessions in which there would naturally be fewer behavioural counts and fewer opportunities for reflections. Also, the context in which the MI took place, namely at a “teachable moment”, could explain the low change talk counts versus the high sustain talk counts. These results may also have arisen because the LHWs had not yet acquired much experience in MI counselling: some LHWs applied the newly learnt skills for the first time in a real patient setting at the time of the selected MI recording. Also, the LHWs often assumed an expert role thus leading to low scores for the “partnership” attribute. In struggling to transition their practice from more traditional counselling to the MI style, LHWs often provided information without asking permission, directed patients on what to do, but seldom let the patients decide on what measures they needed to take to achieve the desired change. These findings are consistent with those of another South African study which also reported low competency of lay counselors in delivering MI despite five days of training [46]. Lay health workers require extended practice and follow-up support to ensure that they are completely competent in MI delivery [47, 48].

Although the South African National TB treatment guidelines clearly stipulate the need for counselling for TB patients on tobacco smoking and drinking [32], it is not clear whether these guidelines have been adhered to or are adopted. Several TB patients stated that they felt listened to and “heard” for the first time in the ProLife MI counselling sessions. Patients said that the MI sessions motivated them to adhere to their TB/HIV treatment and encouraged them to reduce their drinking and smoking. Similarly, LHWs, who all had prior training and experience with counselling, reported having learnt completely new techniques, such as simple listening or showing

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empathy, and expressed surprise at their effectiveness as a communication strategy. The counselling style adopted in MI differs from the paternalistic styles sometimes adopted by lay counsellors in South Africa [46][48]. The positive reception of MI by LHWs and patients combined with existing evidence of the effectiveness of MI [13, 24-26] are encouraging reasons to test this intervention in a definitive trial. For the trial that is following this study, we have provided four days additional MI training with specific emphasis on shortcomings identified during the feasibility study. Contextual challenges, such as lack of space and privacy in clinics, were also addressed.

Similar to the findings of another study in South Africa [49], patients in this study were overall positive about the SMS-messages. The SMS messages served as important reminders and motivators to sustain behaviour change. Many patients wanted to receive the messages for longer. However, some patients said that messages were difficult to understand. We have since revised the translation. In the era of information technology, the World Health Organisation has recommended digital health as one of the strategies to help end TB, but highlights the need for more evidence on its effectiveness [50]. This feasibility study and the planned trial will aid in providing answers about the use of the recommended mHealth (mobile health) for patient care.

Our study was limited by the small sample size. Social desirability bias may have led to overly positive feedback from both LHWs and TB patients: Self-reported reductions in drinking and smoking were not validated. The assessment of randomly selected counselling sessions without considering the timing of those sessions may have led to an under-estimation of the LHWs' overall competency. Furthermore the sample size was too small to determine within LHW improvement of counselling skills over time. The order of delivery of SMS-messages was fixed which may have led to poor synchronisation with the contents of the MI-sessions. During implementation, the custom-designed software package for enrolment and follow-up of study participants linked to the delivery of SMS-messages posed some challenges with system design and poor data synchronisation, often due to erratic internet access at some study sites. The SMS-delivery system was reviewed, another service provider was appointed for the SMS-delivery and a dedicated data manager is closely

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monitoring the SMS-delivery in the roll-out of the actual trial. The challenges identified in this study are not unique [51] and serve as helpful guidance for other researchers and policy makers who plan to introduce digital health interventions in similar settings.

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Table 1. SMS-programme message sequence and IMB-content

MI ses sion	W ee k	D ay	TB disease and treatment adherence	Information, motivation or behavioural skills
1	1	1	Remember to cover your mouth when you cough; this prevents TB germs from spreading in the air.	Information /social motivation
		4	For a complete cure, you will need to take TB medicines daily for at least 6 months.	Information
	2	1	Take your TB medicines always at the same time, like when you brush your teeth. This will help you remember.	Skills (maintain adherence)
		4	It is normal for TB medicines to cause side effects. Common ones include nausea, stomach pains, vomiting, orange urine, joint aches, and skin rash.	Information
	3	1	If you have any problems or concerns about your medication, do not stop. Consult your TB nurse or doctor. They have tips to help you take your pills.	Skills (getting support)
		4	Keep windows open around you, if possible. Fresh air helps reduce TB germs.	Information / social motivation
	4	1	If you stop taking your medicines or don't take them correctly, you can pass TB germs on to others.	Information / social motivation
		4	Ask a family member or friend to help you remember taking TB medicines.	Skills (getting support)
2	5	1	Do take your TB medicines in full dose, even when you feel good. It is the only way to kill TB germs.	Information/ motivation
		4	Adopt a healthy lifestyle. Reduce your chances of ever developing TB again.	Motivation
Tobacco smoking				
	6	1	Replace smoke with a smile. Replace illness with happiness. Quit today.	Motivation
		4	Craving to smoke is temporary but damage to your lungs may be permanent.	Information/ Motivation
	7	1	Within 1 month of quitting, you will cough less and breathe easily.	Information/ Motivation
		4	Alcohol use and smoking will make it harder for your TB to be cured.	Information/ Motivation
	8	1	The best way to quit tobacco is to stop immediately.	Information/skill
		4	It helps to tell your friends and family “I am ready to quit smoking completely”.	Skill (getting support)
3	9	1	After quitting, your body craves for nicotine; this is expected. You may feel constipated, irritable, restless, or lightheaded. This will pass.	Information
Hazardous and harmful drinking				
	9	4	Alcohol damages your liver and your body's protection against infection such as TB and HIV.	Information
	10	1	Cutting down on alcohol will help you recover faster from your TB.	Motivation
		4	Heavy alcohol drinking can make people forget to take their TB medication and they stay sick longer.	Motivation/ Information
	11	1	Drinking less saves you money. Think about what extra money could buy you and your family.	Motivation
		4	Stopping drinking alcohol while you are on TB medication is best. But if you do drink, drink less.	Information
	12	1	It is normal to be nervous when reducing your drinking. It helps to talk to your family, friends, or other people to support you.	Skills (getting support)
		4	If you struggle to reduce your drinking, help is at hand. Talk to your nurse or another health professional. You are not alone.	Skills (getting support)

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Table 2. MI Treatment Fidelity of counselling sessions delivered by LHWs (N=22)

	1st coder		2nd coder		Average both coders	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Global ratings						
Cultivating change talk (1-5)	1.5 (0.7)	1 (1 – 2)	1.5 (0.7)	1 (1 – 2)	1.5 (0.7)	1 (1 – 2)
Softening sustain talk (1-5)	2.8 (1.0)	3 (2 – 4)	2.1 (1.0)	2 (1 – 3)	2.4 (1.0)	2.5 (1.5 – 3.0)
Partnership (1-5)	1.8 (0.7)	2 (1 – 2)	1.6 (0.7)	1.5 (1.0 – 2.0)	1.7 (0.7)	2 (1 – 2)
Empathy (1-5)	2.1 (0.8)	2 (2 – 3)	2.0 (0.8)	2 (1 – 3)	2.1 (0.8)	2 (1 – 3)
Behavioural counts						
Giving information	0.5 (0.7)	0 (0 – 0)	0.5 (0.8)	0 (0 – 1)	0.5 (0.7)	0 (0 – 1)
Questions	16.1 (6.8)	13 (11 – 19)	16.4 (7.4)	15 (12 – 21)	16.2 (7.0)	14.5 (11.5 – 20.0)
Simple reflection	4.8 (5.3)	3.5 (2.0 – 5.0)	5.0 (5.1)	4.5 (2.0 – 6.0)	4.9 (5.1)	4 (2 – 6)
Complex reflection	0.3 (0.8)	0 (0 – 0)	0.7 (1.1)	0 (0 – 1)	0.5 (1.0)	0 (0 – 1)
Affirm	2.3 (1.6)	2.5 (1.0 – 3.0)	2.0 (1.7)	1.5 (1.0 – 3.0)	2.1 (1.6)	2 (1 – 3)
Emphasize Autonomy	2.4 (2.3)	2 (1 – 3)	2.0 (2.1)	1.5 (1.0 – 3.0)	2.2 (2.2)	2 (1 – 3)
Seek collaboration	1.0 (1.0)	1 (0 – 2)	1.4 (1.4)	1 (0 – 2)	1.2 (1.2)	1 (0 – 2)
Persuade ^a	2.7 (4.9)	1 (0 – 3)	2.2 (4.4)	1 (0 – 2)	2.5 (4.6)	1 (0 – 2.5)
Confront	0.9 (2.1)	0 (0 – 0)	0.9 (1.9)	0 (0 – 1)	0.9 (2.0)	0 (0 – 1)
Summary measures						
MI non-Adherent persuade+confront	3.6 (6.3)	2 (0 – 4)	3.1 (5.7)	1 (0 – 3)	3.3 (6.0) ICC 0.97 ^b	1.5 (0.0 – 3.5)
MI adherent collaboration+affirm+emphasizing autonomy	5.7 (3.7)	5.5 (3.0 – 8.0)	5.3 (3.9)	4.5 (2.0 – 8.0)	5.5 (3.7) ICC 0.96 ^b	5.0 (2.5 – 8.0)
Technical global ratings (cultivating change talk+softening sustain talk)/2	2.1 (0.8)	2.0 (1.5 – 2.5)	1.8 (0.7)	2 (1 – 2)	2.0 (0.8) ICC 0.82 ^b	2.0 (1.5 – 2.5)
Relational global ratings (partnership+empathy)/2	2.0 (0.7)	2.0 (1.5 – 2.5)	1.8 (0.7)	1.5 (1.0 – 2.5)	1.9 (0.7) ICC 0.67 ^b	2 (1.3 – 2.5)
Reflection to question ratio (total reflections/total questions)	0.3 (0.5)	0.2 (0.2-0.4)	0.4 (0.5)	0.2 (0.1-0.6)	0.4 (0.4)	0.2 (0.1-0.4)
% Complex reflection [Complex Reflection / (Simple	3.3% (8.1) -		8.6% (13.5) -		6.0% (11.4) -	

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^aPersuade with permission was not assessed as LHWs were not trained specifically in this techniques; ^bIntraclass correlation coefficient

Table 3. TB patients' experiences and satisfaction with the counselling programme and with the counsellor (N=25)

Variable	n (%)
How would you rate the intervention sessions you attended?	
Very unhelpful	2 (8.0)
Somewhat unhelpful	0 (0.0)
Helpful	16 (64.0)
Somewhat helpful	3 (12.0)
Very helpful	4 (16.0)
How much did you enjoy the intervention sessions?	
Not at all	0 (0.0)
A little	0 (0.0)
Quite a lot	4 (16.0)
Very much	10 (40.0)
A great deal	11 (44.0)
Self-reported changes in knowledge, behaviour and health/emotional status as a result of the intervention (yes/no for each question, N=24)	
I drink less alcohol now	13 (54.2)
I smoke less cigarettes now	12 (50.0) ^a
I use drugs less now	0 (0.0)
I quit smoking cigarettes	8 (32.0) ^a
I know more about tobacco's negative effects	16 (66.7)
I know more about alcohol's negative effects	16 (66.7)
I learned a skill I can use	12 (50.0)
I am more adherent to my TB medication	23 (95.8)
I am more adherent to my ART	12 (50.0)
I feel in a better emotional health	21 (87.5)
I feel in a better physical health	19 (79.2)
I started ART as a result of the intervention	8 (33.3)
These sessions did not benefit me in any way	0 (0.0)
Other people would benefit from attending these sessions	11 (44.0)
How much did you like the counsellor's style of interacting with you?	
Not at all	0 (0.0)
A little	0 (0.0)
Quite a lot	3 (12.0)
Very much	4 (16.0)
A great deal	18 (72.0)
Which of the following describes your counsellor? (prompted)	
Knowledgeable	24 (96.0)
Kind	24 (96.0)
Directive	23 (92.0)
Judgemental	1 (4.0)
Helpful	24 (96.0)
Non-judgemental	20 (80.0)
Easy-going	23 (92.0)
Gentle	18 (72.0)

Accepted for Publication in Translational Behavioral Medicine, 28 May 2019.

Trustworthy	24 (96.0)
Good listener	23 (92.0)
Warm	24 (96.0)
Cold	0 (0.0)
Scolding	0 (0.0)
Other (loving, caring and polite)	3 (12.0)

^aThere were 19 current smokers among the respondents, therefore 8/19 or 42.1% of current smokers reported having quit and 12/19 or 63.2 reported having reduced cigarette smoking

Table 4. TB patients' experience and satisfaction with the SMS-programme (N=25)

Variable	n (%)
Reported not having received any messages	2 (8.0)
Perceived helpfulness of this aspect of the intervention	
Very helpful	8 (32.0)
Somewhat helpful	2 (8.0)
Helpful	6 (24.0)
Somewhat unhelpful	1 (4.0)
Very unhelpful	8 (32.0)
Perceived length of messages	
Far too long	3 (12.0)
A bit too long	1 (4.0)
The right length	17 (68.0)
A bit too short	3 (12.0)
Far too short	1 (4.0)
Perceived frequency	
Far too frequently	3 (12.0)
A bit too frequently	0 (0.0)
Frequently enough	17 (68.0)
A bit too infrequently	3 (12.0)
Far too infrequently	2 (8.0)
Messages were easy to understand	
No	17 (68.0)
Yes	8 (32.0)
Perceived duration of receiving the messages	
Should have lasted much longer	8 (32.0)
Should have lasted a bit longer	15 (60.0)
Just right	0 (0.0)
Should have been stopped a bit earlier	0 (0.0)
Should have been stopped much earlier	2 (8.0)
Perceived discomfort if other people had seen the messages	
Extremely comfortable	4 (16.0)
Very comfortable	8 (32.0)
Comfortable	10 (40.0)
A bit uncomfortable	3 (12.0)
Very uncomfortable	0 (0.0)
Understanding of the languages used in the messages	
Very easy to understand/	9 (36.0)
Somewhat easy to understand	1 (4.0)
Easy to understand	13 (52.0)
Somewhat difficult to understand	2 (8.0)
Very difficult to understand	0 (0.0)

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